PATENT COOPERATION TREATY

From the INTERNATIONAL BUREAU

PCT

NOTIFICATION OF ELECTION

(PCT Rule 61.2)

To:

Commissioner
US Department of Commerce
United States Patent and Trademark
Office, PCT
2011 South Clark Place Room
CP2/5C24
Arlington, VA 22202
ETATS-UNIS D'AMERIQUE

in its capacity as elected Office

Date of mailing (day/month/year) 03 January 2001 (03.01.01)	
International application No. PCT/GB00/01807	**Applicant's or agent's file reference** M99/0226/PCT
International filing date (day/month/year) 11 May 2000 (11.05.00)	**Priority date** (day/month/year) 13 May 1999 (13.05.99)
Applicant MCNEIGHT, David, Leslie	

1. The designated Office is hereby notified of its election made:

[X] in the demand filed with the International Preliminary Examining Authority on:

02 December 2000 (02.12.00)

[ ] in a notice effecting later election filed with the International Bureau on:

2. The election [X] was

[ ] was not

made before the expiration of 19 months from the priority date or, where Rule 32 applies, within the time limit under Rule 32.2(b).

The International Bureau of WIPO **34, chemin des Colombettes** **1211 Geneva 20, Switzerland**	Authorized officer Juan Cruz
Facsimile No.: (41-22) 740.14.35	Telephone No.: (41-22) 338.83.38

Copy for the Elected Office (EO/US) PCT/GB00/01807

PATENT COOPERATION TREATY

9/926496

From the INTERNATIONAL BUREAU

PCT

NOTIFICATION OF THE RECORDING OF A CHANGE

(PCT Rule 92bis.1 and Administrative Instructions, Section 422)

To:

MCNEIGHT, David, Leslie
McNeight & Lawrence
Regent House
Heaton Lane
Stockport
Cheshire SK4 1BS
ROYAUME-UNI

Date of mailing (day/month/year)
27 November 2001 (27.11.01)

Applicant's or agent's file reference
M99/0226/PCT

IMPORTANT NOTIFICATION

International application No.
PCT/GB00/01807

International filing date (day/month/year)
11 May 2000 (11.05.00)

1. The following indications appeared on record concerning:

[X] the applicant [ ] the inventor [ ] the agent [ ] the common representative

Name and Address
MICAP LIMITED
Regent House
Heaton Lane
Stockport
Cheshire SK4 1BS
United Kingdom

State of Nationality: GB
State of Residence: GB
Telephone No.:
Facsimile No.:
Teleprinter No.:

2. The International Bureau hereby notifies the applicant that the following change has been recorded concerning:

[X] the person [ ] the name [ ] the address [ ] the nationality [ ] the residence

Name and Address
FLUID TECHNOLOGIES PLC
Science & Innovation Park
Waterside Drive
Swan Meadow Lane
Wigan WN3 5AZ
United Kingdom

State of Nationality: GB
State of Residence: GB
Telephone No.:
Facsimile No.:
Teleprinter No.:

3. Further observations, if necessary:

4. A copy of this notification has been sent to:

[X] the receiving Office
[ ] the International Searching Authority
[ ] the International Preliminary Examining Authority
[ ] the designated Offices concerned
[X] the elected Offices concerned
[ ] other:

The International Bureau of WIPO
34, chemin des Colombettes
1211 Geneva 20, Switzerland

Facsimile No.: (41-22) 740.14.35

Authorized officer
Idhir BRITEL

Telephone No.: (41-22) 338.83.38

PATENT COOPERATION TREATY

From the INTERNATIONAL BUREAU

PCT

NOTIFICATION CONCERNING SUBMISSION OR TRANSMITTAL OF PRIORITY DOCUMENT

(PCT Administrative Instructions, Section 411)

To:

MCNEIGHT, David, Leslie
McNeight & Lawrence
Regent House
Heaton Lane
Stockport
Cheshire SK4 1BS
ROYAUME-UNI

Date of mailing (day/month/year) 23 July 2000 (23.07.00)	
Applicant's or agent's file reference M99/0226/PCT	**IMPORTANT NOTIFICATION**
International application No. PCT/GB00/01807	International filing date (day/month/year) 11 May 2000 (11.05.00)
International publication date (day/month/year) Not yet published	Priority date (day/month/year) 13 May 1999 (13.05.99)
Applicant MICAP LIMITED et al	

1. The applicant is hereby notified of the date of receipt (except where the letters "NR" appear in the right-hand column) by the International Bureau of the priority document(s) relating to the earlier application(s) indicated below. Unless otherwise indicated by an asterisk appearing next to a date of receipt, or by the letters "NR", in the right-hand column, the priority document concerned was submitted or transmitted to the International Bureau in compliance with Rule 17.1(a) or (b).

2. This updates and replaces any previously issued notification concerning submission or transmittal of priority documents.

3. An **asterisk(*)** appearing next to a date of receipt, in the right-hand column, denotes a priority document submitted or transmitted to the International Bureau but not in compliance with Rule 17.1(a) or (b). In such a case, **the attention of the applicant is directed** to Rule 17.1(c) which provides that no designated Office may disregard the priority claim concerned before giving the applicant an opportunity, upon entry into the national phase, to furnish the priority document within a time limit which is reasonable under the circumstances.

4. The **letters "NR"** appearing in the right-hand column denote a priority document which was not received by the International Bureau or which the applicant did not request the receiving Office to prepare and transmit to the International Bureau, as provided by Rule 17.1(a) or (b), respectively. In such a case, **the attention of the applicant is directed** to Rule 17.1(c) which provides that no designated Office may disregard the priority claim concerned before giving the applicant an opportunity, upon entry into the national phase, to furnish the priority document within a time limit which is reasonable under the circumstances.

Priority date	Priority application No.	Country or regional Office or PCT receiving Office	Date of receipt of priority document
13 May 1999 (13.05.99)	9911037.1	GB	13 July 2000 (13.07.00)

The International Bureau of WIPO
34, chemin des Colombettes
1211 Geneva 20, Switzerland

Facsimile No. (41-22) 740.14.35

Authorized officer

Taïeb Akremi

Telephone No. (41-22) 338.83.38

PATENT COOPERATION TREATY

From the INTERNATIONAL BUREAU

PCT

NOTICE INFORMING THE APPLICANT OF THE COMMUNICATION OF THE INTERNATIONAL APPLICATION TO THE DESIGNATED OFFICES

(PCT Rule 47.1(c), first sentence)

To:
MCNEIGHT, David, Leslie
McNeight & Lawrence
Regent House
Heaton Lane
Stockport
Cheshire SK4 1BS
ROYAUME-UNI

Date of mailing (day/month/year) 23 November 2000 (23.11.00)	
Applicant's or agent's file reference M99/0226/PCT	**IMPORTANT NOTICE**

International application No.	**International filing date** (day/month/year)	**Priority date** (day/month/year)
PCT/GB00/01807	11 May 2000 (11.05.00)	13 May 1999 (13.05.99)

Applicant
MICAP LIMITED et al

1. Notice is hereby given that the International Bureau has communicated, as provided in Article 20, the international application to the following designated Offices on the date indicated above as the date of mailing of this Notice:
   AU,KP,KR,US

   In accordance with Rule 47.1(c), third sentence, those Offices will accept the present Notice as conclusive evidence that the communication of the international application has duly taken place on the date of mailing indicated above and no copy of the international application is required to be furnished by the applicant to the designated Office(s).

2. The following designated Offices have waived the requirement for such a communication at this time:
   AE,AL,AM,AP,AT,AZ,BA,BB,BG,BR,BY,CA,CH,CN,CR,CU,CZ,DE,DK,DM,EA,EE,EP,ES,FI,GB,GD,
   GE,GH,GM,HR,HU,ID,IL,IN,IS,JP,KE,KG,KZ,LC,LK,LR,LS,LT,LU,LV,MA,MD,MG,MK,MN,MW,MX,
   NO,NZ,OA,PL,PT,RO,RU,SD,SE,SG,SI,SK,SL,TJ,TM,TR,TT,TZ,UA,UG,UZ,VN,YU,ZA,ZW
   The communication will be made to those Offices only upon their request. Furthermore, those Offices do not require the applicant to furnish a copy of the international application (Rule 49.1(a-bis)).

3. Enclosed with this Notice is a copy of the international application as published by the International Bureau on
   23 November 2000 (23.11.00) under No. WO 00/69440

REMINDER REGARDING CHAPTER II (Article 31(2)(a) and Rule 54.2)

If the applicant wishes to postpone entry into the national phase until 30 months (or later in some Offices) from the priority date, a **demand for international preliminary examination** must be filed with the competent International Preliminary Examining Authority before the expiration of 19 months from the priority date.

It is the applicant's sole responsibility to monitor the 19-month time limit.

Note that only an applicant who is a national or resident of a PCT Contracting State which is bound by Chapter II has the right to file a demand for international preliminary examination.

REMINDER REGARDING ENTRY INTO THE NATIONAL PHASE (Article 22 or 39(1))

If the applicant wishes to proceed with the international application in the **national phase**, he must, within 20 months or 30 months, or later in some Offices, perform the acts referred to therein before each designated or elected Office.

For further important information on the time limits and acts to be performed for entering the national phase, see the Annex to Form PCT/IB/301 (Notification of Receipt of Record Copy) and Volume II of the PCT Applicant's Guide.

Th International Bureau f WIPO
34, chemin des Colombettes
1211 Geneva 20, Switzerland

Facsimile No. (41-22) 740.14.35

Authorized officer
J. Zahra

Telephone No. (41-22) 338.83.38

14

PATENT COOPERATION TREATY

REC'D 12 SEP 2001

WIPO PCT

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
M99/0226/PCT		
International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/GB00/01807	11/05/2000	13/05/1999
International Patent Classification (IPC) or national classification and IPC A61K31/465		
Applicant MICAP LIMITED et al.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 8 sheets, including this cover sheet.

   ☐ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the report
   - II ☐ Priority
   - III ☒ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV ☐ Lack of unity of invention
   - V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations suporting such statement
   - VI ☒ Certain documents cited
   - VII ☒ Certain defects in the international application
   - VIII ☒ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
02/12/2000	10.09.2001
Name and mailing address of the international preliminary examining authority: European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized officer Hornich, E Telephone No. +49 89 2399 8721

Form PCT/IPEA/409 (cover sheet) (January 1994)

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/GB00/01807

I. Basis of the report

1. With regard to the **elements** of the international application *(Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17))*:
Description, pages:

1-5 as originally filed

Claims, No.:

1-16 as originally filed

Drawings, sheets:

1/1 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
- ☐ the claims, Nos.:

☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

   (Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

   ☐ the entire international application.

   ☒ claims Nos. 4.

because:

   ☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination (*specify*):

   ☒ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. 4 are so unclear that no meaningful opinion could be formed (*specify*):
   see separate sheet

   ☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

   ☐ no international search report has been established for the said claims Nos. .

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

   ☐ the written form has not been furnished or does not comply with the standard.

   ☐ the computer readable form has not been furnished or does not comply with the standard.

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

   Novelty (N) Yes: Claims 3, 11

	No:	Claims	1, 2, 5-10, 12-16
Inventive step (IS)	Yes:	Claims	3
	No:	Claims	11
Industrial applicability (IA)	Yes:	Claims	1-16
	No:	Claims	

2. Citations and explanations
see separate sheet

VI. Certain documents cited

1. Certain published documents (Rule 70.10)

and / or

2. Non-written disclosures (Rule 70.9)

see separate sheet

VII. Certain defects in the international application

The following defects in the form or contents of the international application have been noted:
see separate sheet

VIII. Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:
see separate sheet

SECTION III

1. Claim 4 of the present application involves unclarity in the sense of **Art. 6 PCT**, as neither the claimed mixture nor the individual ingredients (diluent, empty cells) are clearly characterized.

SECTION V

2.1 Reference is made to the following documents:

D1: GB-A-2 299 756
D2: GB-A-2 171 906

2.2 Document **D3** was not cited in the international search report. A copy of the document is appended hereto.

D3: K.H. BAUER, K.-H. FRÖMMING, C. FÜHRER: 'Pharmazeutische Technologie', 1991, GEORG THIEME VERLAG, STUTTGART, NEW YORK, p. 341 f.

3. Novelty (**Art. 33(2) PCT**)

3.1 Document **D1** discloses *pastilles* containing *nicotine* in an acacia gum or gelatine base *to be retained in the mouth whilst dissolving* and which may be formed into breakable bars or be cigarette shaped. *Flavourings* or/and *vitamins* may be added. (abstract; fig., p. 1, first and last paragraph; p. 2, l. l. 4 and 7-9; p. 3, paragraphs 2 + 3; p. 5, paragraphs 2 + 3; claims 1, 3, 4, 9, 13, 14, 16, 17).

The described *preparation process* (p. 4, l. 11-22) is such that implicitly *microcapsules* encapsulating nicotine result therefrom (see **D3**, 'Mikrokapseln, Herstellungsverfahren').

Thus, **D1 anticipat s** the subject-matter of claims 1, 2, 5-10 and 12-15.

3.2 Document **D2** describes *oral* or *transdermal* delivery devices for continuous, controlled release of e.g. *nicotine*, which is contained in *microcapsules* and released (dissolved!) therefrom when in contact with the skin or the mucosa (abstract; p. 1, l. 69-71; p. 2, l. 69-94 and l. 111-122; p. 3, l. 58f.; claims 1-3, 7 and 8).

Thus, **D2** is **prejudicial to the novelty** of claims 1, 2, 5 and 16.

3.3 To conclude, claims 1, 2, 5-10 and 12-16 are **not novel**.

4. Inventive Step **(Art. 33(3) PCT)**

4.1 The aim of the present disclosure is to *avoid the problems associated with nicotine delivery systems known from the prior art*, namely *lozenges*, which involve 'formulation problems leading to an uncertain final dose', *gums* ('social unacceptableness') and *patches*, which are aesthetically not pleasing.

However, **D1** has already faced the above-mentioned problems, and the pastilles disclosed within **D1** have already overcome these problems involved with other nicotine-containing delivery systems.

Thus, the remaining (objective) problem of the present application is the *provision of further delivery systems*.

As the use of *yeast cells* (present claim 3) as *reservoir for nicotine* (as 'microcapsules') *is a not obvious alternative* to the preparations of microcapsules, containing nicotine, in the common sense, as described e.g. in the above-cited documents **D1** and **D2**, an **inventive step** can be **acknowledged** for the subject-matter of claim 3.

4.2 However, as one of the objectives of the present application is to avoid the *problems associated with chewing gums*, the subject-matter of claim 11 relating to a chewing gum does **n t involv an inv ntiv st p.**

5. Industrial Applicability **(Art. 33(4) PCT)**

Claims 1-16 fulfil the requirements of industrial applicability.

SECTION VI

6. Certain published documents (Rule 70.10)

Application No Patent No	Publication date (day/month/year)	Filing date (day/month/year)	Priority date (valid claim) (day/month/year)
DE 19856432 (**D4**)	15/06/00	08/12/98	

D4 discloses *nanoparticles* (-capsules) containing active agents (e.g. *nicotine*) used for the preparation of formulations suitable for e.g. *oral* or *transdermal* application.

Therefore, **D4** would be novelty-destroying for the present claims 1, 2, 5-9 and 16.

SECTION VII

7. Within the passages of the description concerning figures 2 and 3, there is reference made to numbers which, however, cannot be found in the figures.

SECTION VIII

8. '*Nicotine solvent*' being part of the subject-matter of claim 1 involves unclarity in the sense of **Art. 6 PCT** as it is not evident *what kind of solvents* should be comprised by that definition.

The same applies to claims 2-16 due to their dependence on claim 1.

9. It is furthermore not obvious what should be understood by the wording ' ... nicotine *solvent* comprises *fatty tissue of the buccal cavity*' (claim 2), **Art. 6 PCT**.

   'Fatty tissue' appears not to be a solvent in the common sense.

10. A further objection under **Art. 6 PCT** concerns claim 9 of the present application, as it contains subject-matter which is defined by a *result to be achieved*. Thus, the claim lacks clarity as a claim should be clear and concise and define the matter for which protection is sought in terms of the technical features of the invention (**Art. 6 and Rule 6.3b)i),ii) PCT**).

11. The dependence of claim 13 on claim *23* involves unclarity (**Art. 6 PCT**) as claim 23 does not exist in the present application.

PCT W INTELLECTUAL PROPERTY ORGANIZATION
International Bureau

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 7 : A61K 31/465, 9/50

A2

(11) International Publication Number: WO 00/69440

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(30) Priority Data:
9911037.1 13 May 1999 (13.05.99) GB

(71) Applicant *(for all designated States except US)*: MICAP LIMITED [GB/GB]; Regent House, Heaton Lane, Stockport, Cheshire SK4 1BS (GB).

(72) Inventor; and
(75) Inventor/Applicant *(for US only)*: MCNEIGHT, David, Leslie [GB/GB]; Brow Top, Lees Lane, Wilmslow, Cheshire SK9 2LR (GB).

(74) Agents: MCNEIGHT, David, Leslie et al.; McNeight & Lawrence, Regent House, Heaton Lane, Stockport, Cheshire SK4 1BS (GB).

(81) Designated States: AE, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CR, CU, CZ, DE, DK, DM, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

Published
Without international search report and to be republished upon receipt of that report.

(54) Title: NICOTINE DELIVERY SYSTEMS

(57) Abstract

There is disclosed a delivery system for nicotine comprising nicotine encapsulated in a microcapsule system which releases the encapsulated nicotine on contact of the microcapsules with a nicotine solvent.

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

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NICOTINE DELIVERY SYSTEMS

This invention relates to delivery systems for nicotine.

Nicotine is commonly taken in the form of smoking tobacco, in cigarettes, principally, cigars and pipe tobacco. To a lesser extent, tobacco, or a preparation from it, is chewed. More rarely, nowadays, is snuff taken. Smoking is declared to be injurious to health, though nicotine itself, in appropriate quantity, is not harmful in the way smoking is, which is due to components other than the nicotine in cigarette smoke and may even be beneficial - it is reported on numerous occasions as aiding concentration.

Though some question it, nicotine is generally regarded as addictive - certainly, increasing taxes on tobacco, Government health warnings and high profile lawsuits brought against tobacco companies by those made terminally ill, or their bereaved, seem to do little to reduce consumption.

There are several products commercially available to help those wishing to quit smoking. These take the form of tablets, chewing gum and patches, all of which are intended to deliver nicotine without the generation of smoke and its associated carcinogenic or otherwise harmful components.

A problem with formulating such products is that nicotine itself is a quite volatile liquid with a boiling point as low as 123° - 125°C at atmospheric pressure, and this makes it difficult to incorporate in products on account of evaporation losses during formulation and the need to seal the products against evaporation of the nicotine for a reasonable shelf life. At the same time, the nicotine must be readily released on use - in the mouth, in the case of gum or lozenge, or through the skin in the case of a patch.

The manner of injection of nicotine is by dissolving in fatty tissue. Nicotine is not readily absorbed in the gut, and no product is intended to be swallowed.

Patches are, of course, somewhat clinical, and while no doubt quite effective, not aesthetically pleasing. Gum is widely regarded as anti-social, often as much so as smoking - there is a disposal problem involved with gum which by and large its users ignore, which has led to its being outlawed in Singapore, a measure which other countries may well follow. Of all the approaches, the most aesthetically acceptable - lozenges, which leave nothing to dispose of and which can be sucked without the sometimes highly objectionable masticating movements - are perhaps the most difficult to formulate, requiring usually elevated temperature processing, leading to nicotine loss through evaporation and an uncertain final dose in the lozenge, and special protection against evaporation from the finished product, if a reasonable shelf life is to be had.

The present invention provides a nicotine delivery system that avoids problems of the prior art and which can give rise to improved products across the available range, but particularly in regard to the lozenge.

The invention comprises a delivery system for nicotine comprising nicotine encapsulated in a microcapsule system which releases the encapsulated nicotine on contact of the microcapsules with a nicotine solvent.

The nicotine solvent that may be targeted could be the fatty tissue of the buccal cavity.

The microcapsules may comprise yeast cells. The system may comprise a mixture of cells charged with nicotine and diluent, empty cells.

The system may be presented in a solid carrier from the surface of which microcapsules are gradually released for controlled delivery.

The solid carrier may comprise a saliva-soluble or dispersible substance, and may comprise a lozenge, which may be sugar-based. The lozenge may have such a size, solubility and charge of nicotine that it delivers a dosage of nicotine, in use over a time period between 4 and 20 minutes, equivalent to that delivered by a cigarette. The lozenge may be elongate, between 5 and 20 cm in length and snappable as by having preferential snapping positions into a number of portions each capable of comfortable accommodation in the mouth.

The solid carrier may, however, comprise a chewing gum.

The system may comprise a flavouring substance, which may also be encapsulated in a microcapsule system, and may also comprise a vitamin supplement, which also may be encapsulated in a microcapsule system.

The system may be comprised in a patch.

Nicotine delivery systems according to the invention and embodiments of products including the same will now be described with reference to the accompanying drawings, in which:-

Figure 1 is a diagrammatic illustration of a method of preparing microencapsulated nicotine;

Figure 2 is a view of one embodiment of a lozenge product; and

Figure 3 is a view of a second embodiment of a lozenge product.

Figure 1 of the drawings illustrate a method for preparing a delivery system for nicotine comprising nicotine encapsulated in a microcapsule system which releases the encapsulated nicotine on contact of the microcapsules with a nicotine solvent.

Nicotine, in the form of liquid nicotine acid 11, is poured into a mixing vessel 12 with a paddle 13. A measured amount of nicotine is mixed into a given volume of yeast cells 14 in order to give a reasonably concentrated absorption of nicotine into each yeast cell. A suitable mix is 25 g nicotine, 50 g of yeast cells, and 100 g of water. This is stirred for 1-24 hours at about 40°C. Cells are removed by centrifugation and dried. An expected loading is between 25 and 60% by weight of nicotine into the cells, depending on the mix used.

The thus nicotine loaded yeast cells 14 are then poured from the vessel 12, in a second stage of the process, into a larger volume of yeast cells 14 in a second mixing vessel 15, also with a paddle 13, and the mixture stirred.

Thus will a desired concentration of nicotine encapsulated in yeast cells be obtained.

The mixed loaded and diluent yeast cells 14 are then incorporated into products with appropriate quantities of the yeast to give the desired nicotine dose in the product.

Two such products are illustrated in Figures 2 and 3.

Figure 2 illustrates an ingot-shaped candy bar 21 which might be some 9 or 10 cm long so as to fit into a packet such as cigarettes are sold in. The bar 21 has transverse grooves 22 enabling it to be snapped into bite-size pieces.

Figure 3 illustrates a similar product 31, this time shaped more like a cigarette, again with grooves 32 for snapping. The presentations of Figures 2 and 3 were first suggested in GB 2 299 756 A.

These products, which are quite similar to cigarettes and which may be used either as aids to quitting smoking or as cigarette substitutes where smoking is not permitted, will, by virtue of their loaded yeast content, contain an equivalent nicotine does to that delivered by smoking a cigarette.

Flavourings such for example as mint, Scotch whisky, Cognac or menthol can also be added, again encapsulated in similar fashion to the yeast, as can other beneficial agents such as vitamin supplements.

CLAIMS

1. A delivery system for nicotine comprising nicotine encapsulated in a microcapsule system which releases the encapsulated nicotine on contact of the microcapsules with a nicotine solvent.

2. A nicotine delivery system according to claim 1, in which the nicotine solvent comprises fatty tissue of the buccal cavity.

3. A nicotine delivery system according to claim 1 or claim 2, in which the microcapsules comprise yeast cells.

4. A nicotine delivery system according to claim 3, comprising a mixture of cells charged with nicotine and diluent, empty cells.

5. A nicotine delivery system according to any one of claims 1 to 4, presented in a solid carrier from the surface of which microcapsules are gradually released for controlled delivery.

6. A system according to claim 5, in which the solid carrier comprises a saliva-soluble or dispersible substance.

7. A system according to claim 6, in which the solid carrier comprises a lozenge.

8. A system according to claim 7, in which the lozenge is sugar-based.

9. A system according to claim 7 or claim 8, having such a size, solubility and charge of nicotine that it delivers, in use over a time period between 4 and 20 minutes, an amount of nicotine equivalent to that delivered by a cigarette.

10. A system according to claim 9, in which the lozenge is elongate, between 5 and 20 cm in length and snappable as by having preferential snapping positions into a number of portions each capable of comfortable accommodation in the mouth.

11. A system according to claim 5, in which the solid carrier comprises a chewing gum.

12. A system according to any one of claims 1 to 11, comprising a flavouring substance.

13. A system according to claim 23, in which the flavouring substance is also encapsulated in a microcapsule system.

14. A system according to any one of claims 1 to 13, comprising a vitamin supplement.

15. A system according to claim 14, in which the vitamin is also encapsulated in a microcapsule system.

16. A system according to any one of claims 1 to 4, comprised in a patch.

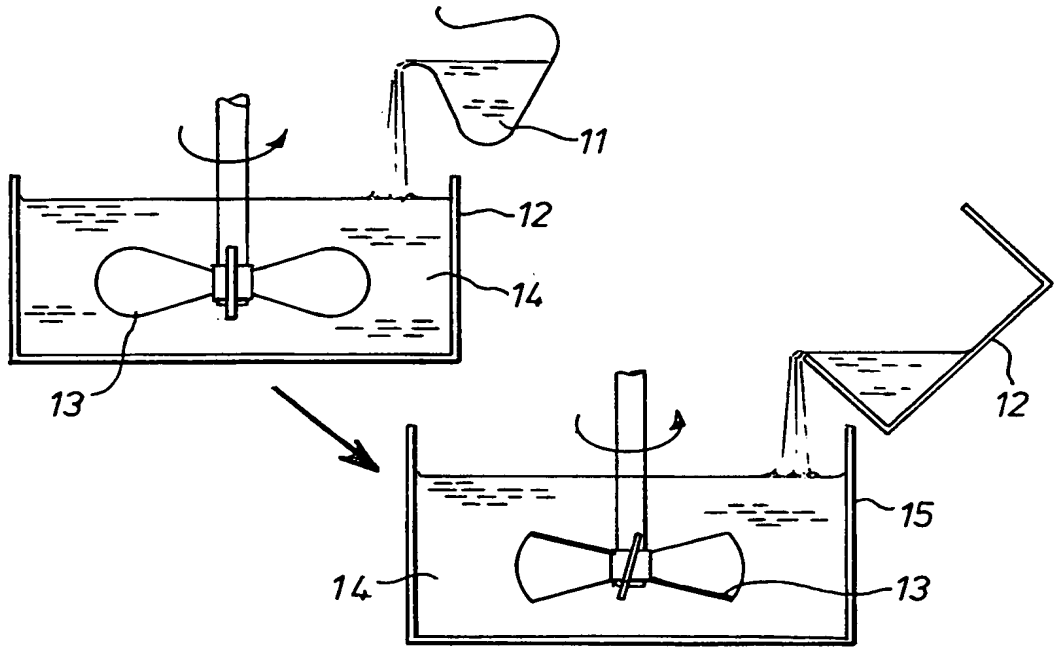

FIG.1

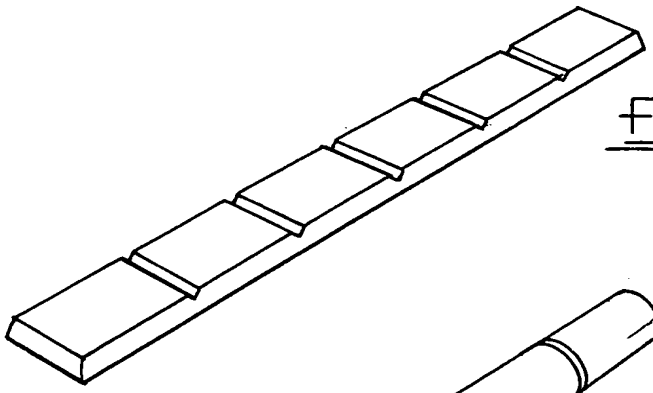

FIG. 2

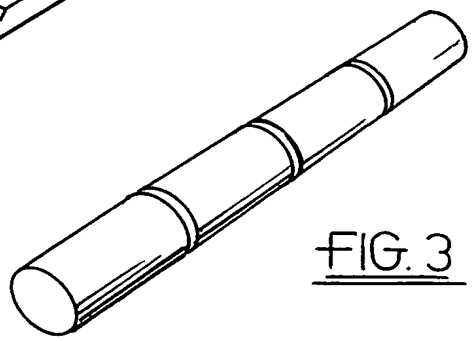

FIG. 3